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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,433	12/14/2005	Alain Troesch	126239	8787

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EXAMINER	
ARCHIE, NINA	
ART UNIT	**PAPER NUMBER**
1645	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/560,433	TROESCH ET AL.	
	Examiner	Art Unit	
	Nina A. Archie	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1-2, and 6*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) *3-5 and 7-10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/9/2006 and 9/4/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Drawings

2. The drawings in this application have been accepted. No further action by Applicant is required.

Specification

3. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Information Disclosure Statement

4. The information disclosure statements filed on 6/9/2006 and 9/4/2007 has been considered. Initialed copies are enclosed.

Election/Restrictions

5. Applicant's election with traverse of Group I (claims 1, 2, and 6) is acknowledged. The traversal is on the ground(s) that the Office Action fails to establish a prima facie case that there is a lack of unity of invention among the Groups of claims. A lack of unity of invention may be apparent "a priori," that is, before considering the claims in relation to any prior art, or may only become apparent "a posteriori," that is, after taking the prior art into consideration. See MPEP§ 1850(II), quoting International Search and Preliminary Examination Guidelines ("ISPE") 10.03. Lack of a priori unity of invention only exists if there is no subject matter common to all claims, Id. If a priori unity of invention exists between the claims, or, in other words, if there is subject matter common to all the claims, a lack of unity of invention may only be established a

posteriori by showing that the common subject matter does not define a contribution over the prior art. Id. Furthermore, as ISPE 10.06 provides, unity of invention only needs to be determined in the first place among independent claims, and not the dependent claims. A priori unity of invention exists among independent claims 1, 3, 4, 8 and 9. Independent claim 1 recites, in part, "at least 10 nucleotide motifs of SEQ ID No. 1 and/or...at least 10 nucleotide motifs of SEQ ID No. 2." Independent claims 3 and 8 recite, in part, "at least 15 nucleotide motifs of SEQ ID No. 1" (which is a subset of" at least 10 nucleotide motifs of SEQ ID No. 1," as recited in claim 1); and independent claims 4 and 9 recite, in part, "at least 20 nucleotide motifs of SEQ ID No. 2" (which is a subset of at least 10 nucleotide motifs of SEQ ID No. 2," as recited in claim 1). Accordingly, subject matter common to all of the independent claims 1, 3, 4, 8 and 9 is "at least 10 nucleotide motifs of SEQ ID No. 1 and/or...at least 10 nucleotide motifs of SEQ ID No. 2," as recited by claim 1 (emphasis added).
Accordingly, all the claims share common subject matter and, therefore, a priori unity of invention exists among all the claims. Thus, for the present application, a lack of unity of invention may only be determined a posteriori, or in other words, after a search of the prior art has been conducted and it is established that all the elements of the independent claims are known. See ISPE 10.07 and 10.08. The Office Action does not establish that each and every element of the subject matter that is common to independent claims 1, 3, 4, 8 and 9 is known in the prior art. The Office Action fails to provide Applicants with any references disclosing "at least 10 nucleotide motifs of SEQ ID No. 1 and/or...at least 10 nucleotide motifs of SEQ ID No. 2." Nowhere in any reference attached to the Office Action, including Kimmerly, which page 2 of the Office Action cites as allegedly disclosing "at least 15 nucleotide motifs of SEQ ID NO: 2," is the subject matter that is common to independent claims 1, 3, 4, 8 and 9 disclosed. Therefore, Applicants respectfully submit that lack of unity of invention has not been established, and thus a restriction requirement based on a lack of unity of invention is improper.

This is not found persuasive. The lack of unity dated on 8/4/08 is based on the claims filed. The special technical feature of Group II is an amplification primer,

characterized in that it comprises at least 20 nucleotide motifs of SEQ ID NO: 2. The technical feature of Group I is anticipated by et al Kimmerly WJ WO200134809-A2. Date May 17, 2001. Kimmerly teaches an amplification primer, characterized in that it comprises at least 20 nucleotide motifs of SEQ ID NO: 2 (see abstract claim 8 STIC Results). The technical feature of Group II is drawn to an amplification primer, characterized in that it comprises at least 20 nucleotide motifs of SEQ ID NO: 2 are known in the art. Therefore, unity of invention is lacking.

The requirement is still deemed proper and is therefore made FINAL.

Claims 3-5 and 7-10 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the response filed 8-4-08.

Claim Objections

5. Claim 6 is objected to because of the following informalities: The genus Staphylococcus is misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 102 and 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-2 and 6 rejected under 35 U.S.C. 102(b) as being anticipated by Kunsch et al EP0786519 Date 7/30/1997.

Claims 1-2 and 6 are drawn to a method for detecting and/or identifying bacteria of the genus Staphylococcus in a biological sample, comprising: A. extracting a nucleic acid material of the bacteria of the genus Staphylococcus, B. amplifying at least one target sequence of the nucleic acid material of the bacteria of the genus Staphylococcus by using at least one amplification primer comprising at least 10 nucleotide motifs of SEQ ID No. 1 in order to obtain amplicons of the target sequence, and C. determining the presence of bacteria of the genus Staphylococcus is by detecting said amplicons, further comprising: D. identifying the bacterial species belonging to the genus Staphylococcus by using at least one hybridization probe able to hybridize with a target sequence specific for a bacterial species belonging to the genus Staphylococcus.

Kunsch et al teach a computer readable medium having recorded thereon a nucleotide sequence of the Staphylococcus aureus genome. Kunsch et al teach a kit for analyzing samples for the presence of polynucleotides derived from Staphylococcus aureus, comprising at least one polynucleotide containing a nucleotide sequence of any one of the fragments SEQ ID NOS: 1-5,191 or a degenerate variant that will hybridize to a staphylococcus aureus polynucleotide under stringent hybridization conditions. Kunsch et al teach a method for identifying commercially important nucleic acid fragments of the Staphylococcus aureus genome comprising the step of comparing a database comprising the nucleotide sequences depicted in SEQ ID NOS: 1-5,191, a representative fragment thereof with a target sequence to obtain a nucleic acid molecule comprised of a complementary nucleotide sequence to said target sequence, wherein said target sequence is not randomly selected. Kunsch et al teach a nucleic acid molecule being a homolog of any of the fragments of the Staphylococcus aureus genome of SEQ ID NOS:1-5,191, wherein said nucleic acid molecule is produced by a process comprising the steps of: (a) screening a genomic DNA library using as a probe a target sequence defined by any of SEQ ID NOS:1-5,191 including fragments thereof; (b) identifying members of said library which contain sequences that hybridize to said target sequence; (c) isolating the nucleic acid molecules from said members identified in step (b). Kunsch et al teach various fragments such as SEQ ID Nos: 4375, 4286, 4162, 3633, 3802, 3550, 3828, 3694, 3589, 1635, 3630, 3539, and 3194 which all read on SEQ ID NO: 1 which also consist of the Staphylococcus aureus genome, can be used which are used to prepare PCR primers for a variety of uses. Kunsch et al teach that the PCR primers are preferably at least 15 bases, and more preferably at least 18 bases in length. Kunsch et al teach SEQ ID NO: 1 (See STIC RESULTS see SEQ ID Nos: 4375, 4286, 4162, 3633, 3802, 3550, 3828, 3694, 3589, 1635, 3630, 3539, and 3194) comprising at least 10/20 nucleotide motifs (see claims and STIC RESULTS).

Thus Kunsch et al inherently teach a method for detecting and/or identifying bacteria of the genus Staphylococcus in a biological sample, comprising: A. extracting a nucleic acid material of the bacteria of the genus Staphylococcus, B. amplifying at least one target sequence of the nucleic acid material of the bacteria of the genus

Staphylococcus by using at least one amplification primer comprising at least 10 nucleotide motifs of SEQ ID No. 1 in order to obtain amplicons of the target sequence, and C. determining the presence of bacteria of the genus Staphylococcus is by detecting said amplicons, further comprising: D. identifying the bacterial species belonging to the genus Staphylococcus by using at least one hybridization probe able to hybridize with a target sequence specific for a bacterial species belonging to the genus Staphylococcus. Kunsch et al teach a method of detecting and/or identifying bacteria of the genus Staphylococcus, comprising contacting a biological sample with at least one primer at least 15 nucleotide motifs of SEQ ID NO: 1.

7. Claims 1, 2, and 6 rejected under 35 U.S.C. 103(a) as being unpatentable over Kunsch et al EP0786519 Date 7/30/1997 in view of Sambrook et al. Molecular cloning: A Laboratory Manual 1st edition, 1989 chapter 10 and chapter 11.45-11.57, 11.12-11.13.

Claims 1, 2, and 6 drawn to teach a method for detecting and/or identifying bacteria of the genus Staphylococcus in a biological sample, comprising: A. extracting a nucleic acid material of the bacteria of the genus Staphylococcus, B. amplifying at least one target sequence of the nucleic acid material of the bacteria of the genus Staphylococcus by using at least one amplification primer comprising at least 10 nucleotide motifs of SEQ ID No. 1 in order to obtain amplicons of the target sequence, and C. determining the presence of bacteria of the genus Staphylococcus is by detecting said amplicons, further comprising: D. identifying the bacterial species belonging to the genus Staphylococcus by using at least one hybridization probe able to hybridize with a target sequence specific for a bacterial species belonging to the genus Staphylococcus.

Kunsch et al is relied upon as set forth supra. Kunsch et al does not specifically teach that an amplification primer of at least 10 nucleotide motifs of SEQ ID NO: 1.

Sambrook et al teaches the preparation of DNA probes and the conditions for hybridizations of oligonocleotide probes.

Thus as to claims 1, 2, and 6, it would have been prima facie obvious to one of ordinary skill in the art at the time the instant invention was made having the sequence

disclosed by Kunsch et al or its complement to design probes for the detection and or identification of bacteria belonging to the genus Staphylococcus.

Status of the Claims

8. No claims are allowed.

Claims 1, 2, and 6 are rejected.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina A. Archie whose telephone number is 571-272-9938. The examiner can normally be reached on Monday-Friday 8:30-5:00p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner supervisor, Robert Mondesi can be reached on 571-272-0956 and Robert Mondesi at 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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